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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/810,258 | 03/26/2004 | Qianjin Hu | 433112001000 | 8314 |
| 25226 | 7590 | 10/19/2005 | EXAMINER | |
| MORRISON & FOERSTER LLP | | | HINES, JANA A | |
| 755 PAGE MILL RD | | | ART UNIT | |
| PALO ALTO, CA 94304-1018 | | | PAPER NUMBER | |

1645

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/810,258

Applicant(s)

HU ET AL.

Examiner

Ja-Na Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-25 and 29-31 are drawn to a multi-array system, a method of making a multi-array system and a kit comprising the multi-array system, classified in class 435, subclass 287.3.
 - II. Claims 1 and 26-27 are drawn to an apparatus comprising a multi-array system and a temperature control unit, classified in class 435, subclass 283.1.
 - III. Claim 28 is drawn to a method of performing an assay on a plurality of biomolecules simultaneously, classified in class 435, subclass 4.
2. The inventions are distinct, each from the other because of the following reasons:
 - ii) Inventions I and II are patentably different products. The inventions are distinct, each from the other because of the following reasons: Although there are no provisions under the section for "Related Inventions" in M.P.E.P. 806.05 for inventive groups that are directed to different products; restriction is deemed to be proper because these products appear to constitute patentably distinct inventions. Group I is drawn to a multi-array system, a method of making a multi-array system and a kit comprising the multi-array system while Group II is drawn to an apparatus comprising a multi-array system and a temperature control unit. The groups are directed to products that are physically, structurally and functionally different, thus they are patentably distinct from each other. For instance, the apparatus comprising a multi-array system

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and a temperature control unit is unlike the system of Group I. The apparatus of group II comprises a temperature control unit thus one group is not required to practice the other. Each group comprises separate and distinct products and additional components that are not disclosed as being essential to the utility of the invention. Moreover, the specification teaches the multi-array system and the apparatus are separate embodiments, see page 3 of the instant specification.

Furthermore, searching the inventions of groups I and II would impose a serious search burden. The inventions have a separate status in the art as shown by their distinct structure. Thus different system and apparatus require different searches. A search of a multi-array system comprising a substantially enclosed reaction chamber, with sealable opening or having specific substrate materials is not necessary for a determination of novelty and unobviousness of an apparatus comprising a multi-array system and a temperature control unit. Moreover, a full search of a multi-array system, a method of making a multi-array system and a kit comprising the multi-array system is not required to identify the apparatus of group II. Furthermore, the apparatus of group II may be known even if the multi-array system of group I is novel. In addition, the technical literature search for the apparatus of group II and the multi-array system of group I are not coextensive, e.g., the apparatus of group II may be characterized in the technical literature prior to discovery of the multi-array system of group I.

(ii) Inventions I and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as

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claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the method of performing an assay on a plurality of biomolecules simultaneously can be used with a DNA chip including an oligonucleotide array comprised of a number of individual oligonucleotides linked to a solid support. Thus, the process as claimed can be practiced by another materially different apparatus and the inventions are thereby distinct.

Searching the inventions of groups I and III together would impose serious search burden. The inventions of groups I and III have acquired a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the apparatus and the method of performing an assay on a plurality of biomolecules simultaneously are not coextensive. Group I encompasses a multi-array system and therefore is not required for the search of the method of group III. In contrast, the search for groups III would require a text search for a method for performing an assay on a plurality of biomolecules simultaneously and would not necessarily encompass a search for the multi-array system. Moreover, even if the method were known, the multi-array system may be novel and unobvious in view of the preamble or steps drawn to the components within the array.

(iii) Inventions II and III are unrelated because the apparatus and the method are not used or otherwise involved with each other.

3. The inventions of Groups I-III have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search any combination of the inventions of Groups I-III together.

4. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process

claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
October 14, 2005

